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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,805	08/03/2001	Seiichi Shibamura	P21313	7834

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,805	SHIBAMURA ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11, 12, 14-21 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 12, 14-21 and 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed Jan. 2, 2004 is acknowledged. Claims 8-10, 13, 22 were canceled.

Claims 25-36 were added

2. Claims 1-7, 11, 12, 14-21 and 23-36 are pending and examined on the merits.

Claim Rejections Withdrawn:

3. The rejection of claim 10 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in view of the cancellation of claim 10.

4. The rejection of claim 13 under 35 U.S.C. 102(b) as being anticipate by either Mishra (Acta Chimica Hungarica 116(1): 5-12, 1984) or Kapoor (J. of Luminescence, 22: 429-439, 1981) is withdrawn in view of the cancellation of claim 13.

5. The rejection of claim 13 under 35 U.S.C. 102(e) as being anticipated by Klemm (U.S. Patent 5,677,192; Oct. 14, 1997; effective filing date Mar. 18, 1996; cited in IDS) is withdrawn in view of the cancellation of claim 13.

6. The rejection of claims 1, and 10 under 35 U.S.C. 103(a) as being unpatentable over Karandikar (U.S. Patent 6,207,464; issued Mar. 27, 2001; effective filing date June 7, 1995) in

Art Unit: 1642

view of either Mishra (Acta Chimica Hungarica 116(1): 5-12, 1984) or Kapoor (J. of Luminescence, 22: 429-439, 1981) is withdrawn in view of the amendment to claim 1, deleting the reference to a surfactant, and the cancellation of claim 10.

7. The rejection of claims 1, 10, 12, 14, 15 and 24 under 35 U.S.C. 103(a) as being unpatentable over Karandikar (U.S. Patent 6,207,464; issued Mar. 27, 2001; effective filing date June 7, 1995) in view of either Mishra (Acta Chimica Hungarica 116(1): 5-12, 1984) or Kapoor (J. of Luminescence, 22: 429-439, 1981) and further in view of Sykes et al (U.S. 6,313,274; issued Nov. 6, 2001; effective filing date May 25, 1995) is withdrawn in view of the amendment to claims 1, 14 and 15, deleting the reference to a surfactant, and the cancellation of claim 10.

8. The rejection of claims 1, and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Karandikar (U.S. Patent 6,207,464; issued Mar. 27, 2001; effective filing date June 7, 1995) in view of Klemt (U.S. Patent 5,677,192; Oct. 14, 1997; effective filing date Mar. 18, 1996; cited in IDS) is withdrawn in view of the cancellation of claim 8-10 and further in view of the fact that Klemt's teaching do not apply to fluorescent labels, but instead applies to electrochemiluminescence labels.

9. The rejection of claims 1, 10-12, 14, 15 and 24 under 35 U.S.C. 103(a) as being unpatentable over Ito (Bioorganic and Medicinal Chemistry Letters 5(22): 2689-2694, 1995; cited in IDS) in view of Mishra (Acta Chimica Hungarica 116(1): 5-12, 1984) or Kapoor (J. of Luminescence, 22: 429-439, 1981) and further in view of Sykes et al (U.S. 6,313,274; issued

Art Unit: 1642

Nov. 6, 2001; effective filing date May 25, 1995) is withdrawn in view of the amendment to the claims.

New Grounds of Rejection:

10. Claims 1-7, 11, 12, 14-21 and 24-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11, 14, 15, 25, 26 and 33 are indefinite because of the recitation “indocyanine green derivative”. The specification fails to define the metes and bounds of “indocyanine green derivative”, because the term “derivative” can be interpreted as having as little as one molecule in common with indocyanine green. This rejection would be overcome if the claims were to be amended as recited in U.S. Patent 5,968,479, which recites structures to indicate the metes and bounds of claimed compounds.

Claims 27 is indefinite because it is drawn to a composition of claim 25, when claim 25 is drawn to a method.

Claim 30 is indefinite because it is drawn to a method of claim 26, when claim 26 is drawn to a composition.

11. Claims 1-7, 11, 12, 14-21 and 24-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

Art Unit: 1642

claimed invention. The basis for this rejection is that the claims are drawn to compositions comprising antibodies bound with a fluorescent functional group comprising an “indocyanine green derivative which is capable of being excited to cause fluorescence” and to methods using said antibodies, where the specification lacks a definition of “indocyanine green derivative which is capable of being excited to cause fluorescence” so that the claims are drawn to a genus of compounds that lack an adequate description.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is for purposes of the ‘written description’ inquiry, “*whatever is now claimed*” (see page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed.” (See Vas-Cath at page 1116). The description provided in the specification of the genus of “indocyanine green derivative which is capable of being excited to cause fluorescence” appears to be a presentation of preferred examples, but is not a definition of the metes and bounds of the term “indocyanine green derivative”. Therefore, the phrase is open to interpretation, and the phrase “indocyanine green derivative” broadly reads on any molecule that shares at least one molecule in common with indocyanine green.

Because of the breadth of phrase “indocyanine green derivative”, the skilled artisan cannot envision the detailed chemical structure of the encompassed “indocyanine green derivative which is capable of being excited to cause fluorescence” used in the composition and method claims. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making or testing it. One cannot

Art Unit: 1642

describe what one has not conceived. See Fides v. Baird, 30 USPQ2d 1481, 1483. In Fides v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112, is severable from its enablement provision. (See page 1115).

This rejection would be overcome if the claims were amended to recite structures as in the claims of U.S. Patent 5,968,479.

12. Claims 14-21, 23-25, 27-29 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods comprising contacting the tumor cell or the malignant neoplasia of epithelial cells with an antibody that is specific for a tumor cell or a malignant neoplasia of epithelial cells, does not reasonably provide enablement for methods comprising contacting the tumor cell or the malignant neoplasia of epithelial cells with any antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

Art Unit: 1642

The claimed methods are drawn to methods for immunohistochemical staining of tumor cells, or to immunohistochemical diagnosis of malignant neoplasia of epithelial cells. However, the methods steps recite that any antibody may be used, where the antibody is bound with a fluorescent functional group comprising an indocyanine green derivative which is capable of being excited to cause fluorescence. The specification confines its teachings to examples where the antibodies used in the claimed methods are anticancer-antigen antibodies (see page 14 of the specification). Therefore, the breadth of the claims is not commensurate in scope with the scope of the teachings of the specification.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached at (571) 272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
April 19, 2004


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